

REMARKS

The Office Action dated March 4, 2004, has been received and reviewed.

Claims 1-120 were previously pending and under consideration in the above-referenced application.

Claims 1-33 were withdrawn from consideration pursuant to a restriction requirement of February 23, 2004. The election to prosecute claims 34-120 without traverse is hereby acknowledged.

With respect to claims 34-120, the Office has indicated that claims 42, 46, 48-51, 61, 62, 65-69, 78, 80-83, 85-87, 95-99, 100-109, 111, and 116-120 recite allowable subject matter.

Claims 34-41, 43-45, 47, 52-61, 63, 64, 70-74, 76, 77, 79, 84, 88-92, 93, 94, 110, and 112-115 stand rejected.

Reconsideration of the above-referenced application is respectfully requested.

Characterization of the Claims

Please note that the claims of the above-referenced application have been mischaracterized as including "steps." None of the claims of the above-referenced application recites the term "step." Accordingly, none of the claims, by their plain language and the equivalents thereto, should be interpreted or construed as setting forth one or more "steps," as doing so might unduly limit the respective scopes thereof.

Objection to the Specification

The specification has been objected to on the basis that it does not provide support for the recitation in claims 42 and 61 of a process which includes evaluating respiration during first and second ventilation states, with the first ventilation state comprising "bi-directional rebreathing," which includes before, during and after phases.

Claims 42 and 61 have been amended to recite that the first ventilation state comprises rebreathing, which is fully supported by the as-filed specification.

Accordingly, withdrawal of the objection to the specification is respectfully requested.

Claim Objections

Claims 54 and 57 have been objected to on the basis that the term “said,” prior to the recitation of “another first ventilation state,” was omitted. As the term “said” has been removed from all of the claims and, in some instances, replaced with the equivalent term “the,” “the” has been added to both claim 54 and 57 before the recitation of “another first ventilation state.”

Accordingly, it is respectfully requested that the objections to claims 54 and 57 be withdrawn.

Claim 113 has been objected to for reciting “said evaluatings.” Claim 113 has been amended to set forth each “evaluating” element separately.

Therefore, withdrawal of the objection to claim 113 is respectfully requested.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 34-120 have been stand rejected under 35 U.S.C. § 112, second paragraph, for reciting subject matter which is purportedly indefinite.

With respect to the definiteness requirement of the second paragraph of 35 U.S.C. § 112, M.P.E.P. § 2173 provides:

The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph[,] with respect to the claimed invention.

Independent claims 34, 52, 70, 84, 100, and 110 have been rejected on the basis that language recited in the preambles thereof is not further modified by the bodies of these claims. For example, claim 34, which is directed to a “method for noninvasively estimating at least one of a pulmonary capillary blood flow and a cardiac output of a patient” has been rejected for

failing to “recite steps that actually estimate either of pulmonary blood flow or cardiac output.”

Office Action, page 5.

None of 35 U.S.C. § 112, second paragraph, its accompanying rules, or the M.P.E.P. includes a requirement that a claim include every detail that would be necessary to completely effect a method that has been recited in the preamble of the claim. To the contrary, M.P.E.P. § 2111.03 provides that the term “comprising,” which appears at the end of the preamble of each of independent claims 34, 52, 70, 84, 100, and 110, “is inclusive or open-ended and does not exclude additional, unrecited elements . . .”

No additional elements are recited in any of independent claims 34, 52, 70, 84, 100, or 110 because no further claim limitations are necessary to “ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement” thereof. *See* M.P.E.P. § 2173.

Further in this regard, M.P.E.P. § 2173.04 indicates that a claim having clear scope cannot be rejected under 35 U.S.C. § 112, second paragraph, based merely on its breadth.

Again, there is no requirement in the law, the rules, or the guidelines that are provided in the M.P.E.P. that a claim include anything more than the elements that are patentable, so long as the scope of the claim is clear.

For these reasons, it is respectfully requested that the 35 U.S.C. § 112, second paragraph, rejections of independent claims 34, 52, 70, 84, 100, and 110, as well as the rejections of the claims that depend from each of these independent claims, be withdrawn.

Claim 47 has also been rejected under the second paragraph of 35 U.S.C. § 112 on the basis that the recitation that “evaluating respiration of [a] patient during a second ventilation state . . . before initiation of noninvasively estimating . . .,” to which the claim generally applies, is confusing.

Claim 47 has been amended to more precisely recite that the act of “evaluating respiration of [a] patient during a second ventilation state is effected before calculating the pulmonary capillary blood flow or cardiac output of the patient.” By introducing the element of calculating, claim 47 recites, with greater particularity, the relative point in time at which the act of

“evaluating respiration . . . during [the] second ventilation state . . .” is effected during the recited noninvasive estimation method.

Therefore, it is respectfully submitted that, under 35 U.S.C. § 112, second paragraph, claim 47 recites subject matter which is definite and allowable. Accordingly, withdrawal of the 35 U.S.C. § 112, second paragraph, rejection of claim 47 is respectfully requested.

Claim 79 was rejected (see remarks regarding claim 78, which lacks the rejected limitations) on the basis that it recites that a second phase occurs before a first phase, but that independent claim 70, from which claim 79 depends, recites that during the second phase, a change in effective ventilation, which occurs during the first phase, “is removed.”

Claim 70 has been amended to more broadly recite that a change in effective ventilation is not present during the second phase, thereby overcoming any confusion that may have been presented by the subject matter recited in claim 79.

Thus, it is respectfully submitted that, under the second paragraph of 35 U.S.C. § 112, claim 79 recite subject matter which is allowable and, therefore, requested that this rejection be withdrawn.

Rejections Under 35 U.S.C. § 102(e)

Each of claims 34-36, 38-41, 43-45, 47, 52, 53, 58-61, 63, 64, 70, 77, 79, 84, 93, 94, 110, and 113-115 stands rejected under 35 U.S.C. § 102(e).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference which qualifies as prior art under 35 U.S.C. § 102. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Mault

Claims 34, 35, 38-40, 44, 45, and 47 stand rejected under 35 U.S.C. § 102(e) for being drawn to subject matter which is purportedly anticipated by the subject matter described in U.S. Patent 6,517,496 to Mault et al. (hereinafter “Mault”).

As noted at page 7 of the outstanding Office Action, Mault describes a process which includes evaluating respiration during normal breathing for two to three minutes, then evaluating respiration as an increase or decrease in FIO_2 is effected for a period which lasts for less than about 30 to 50 seconds. Col. 6, lines 40-47.

Independent claim 34 is directed to a method which includes “evaluating respiration of [a] patient during a first ventilation state” and “evaluating respiration of the patient during a second ventilation state.” As amended and presented herein, the first and second ventilation states that are recited in independent claim 34 both have durations of “about eighteen to about sixty seconds.”

Mault lacks any express or inherent description of a method which includes evaluating respiration during first and second ventilation states, both of which have respective durations of “about eighteen to about sixty seconds.” Instead, the disclosure of Mault is clearly limited to a method which includes evaluating respiration during a normal breathing period which lasts about two to three minutes and during a change in effective ventilation, which lasts for less than about 30 to 50 seconds. Col. 6, lines 40-47.

Therefore, it is respectfully submitted that Mault does not anticipate each and every element of amended independent claim 34, as would be required to maintain the 35 U.S.C. § 102(e) rejection thereof.

Claims 35, 38-40, 44, 45, and 47 are each allowable, among other reasons, for depending directly from claim 34, which is allowable.

Claim 44 is further allowable because Mault does not expressly or inherently describe that a second ventilation state (identified by the Office as breathing a state in gases that include an increased or decreased FIO_2) in which a patient breathes air. Rather, the disclosure of Mault is limited to breathing gases that include at least 10% more or at least 10% less oxygen than air.

Kück

Claims 34-36, 39-41, 44, 45, 47, 52, 53, 58-61, 63, 64, 70, 77, 79, 84, 93, 94, 110, and 113-115 stand rejected under 35 U.S.C. § 102(e) for reciting subject matter which is allegedly anticipated by the disclosure of U.S. Patent 6,200,271 to Kück et al. (hereinafter “Kück”).

Kück, at col. 9, lines 31-42, describes an exemplary “bi-directional rebreathing” process that includes a “before” phase that last for six seconds (the difference between the time at 40 seconds into the process and the time at 46 seconds into the process). The subsequent “during” phase lasts for about 50 seconds. Col. 9, lines 43-51. Kück is silent as to the specific length of the “after” phase, which occurs following the “during” phase. *See* Col. 9, lines 52-60 (which merely states that the “after” phase “may be of any duration sufficient to facilitate the accurate determination of VCO_2 and $CACO_2$ ”).

Independent claim 52 is drawn to a method for noninvasively estimating at least one of a pulmonary capillary blood flow and a cardiac output of a patient. The method of independent claim 52 includes evaluating respiration of a patient during first and second ventilation states. The second ventilation state immediately follows the first ventilation state. Then, immediately following the second ventilation state, respiration of the patient is evaluated during another first ventilation state. Independent claim 52, as amended and presented herein, also recites that each of the first, second, and another first ventilation states has a duration of about eighteen seconds to about sixty seconds.

Independent claim 110 also recites a method for noninvasively determining at least one of a pulmonary capillary blood flow and a cardiac output of a patient. The method of independent claim 110 includes evaluating respiration of the patient during each of a first phase and a second phase. During the first phase, which lasts for a first duration of time, a change in effective ventilation of the patient is induced. During the second phase, which lasts for a second period of time, the change in effective ventilation is removed. Independent claim 110, as amended and presented herein, also recites that the first and second phases each last for about eighteen seconds to about sixty seconds.

With respect to the subject matter recited in amended independent claims 34, 52, and 110, Kück lacks any express or inherent description of a method which includes evaluating respiration during first and second ventilation states (claims 34 and 52) or phases (claim 110) that each last for about eighteen seconds to about sixty seconds. Instead, the description of Kück is limited to evaluating respiration for a first state that lasts for six seconds, a second state that lasts for about 50 seconds, and a third state that lasts for an undefined period of time.

Therefore, Kück does not anticipate each and every element of any of amended independent claims 34, 52, or 110. Accordingly, it is respectfully submitted that, under 35 U.S.C. § 102(e), amended independent claims 34, 52, and 110 recite subject matter which is allowable over that described in Kück.

Each of claims 35, 36, 39-41, 44, 45, and 47 is allowable, among other reasons, for depending directly or indirectly from claim 34, which is allowable.

Claims 53, 58-61, 63, and 64 are each allowable, among other reasons, for depending either directly or indirectly from claim 52, which is allowable.

Claims 113-115 are each allowable, among other reasons, for depending directly or indirectly from claim 110, which is allowable.

Claim 36 is additionally allowable since Kück does not expressly or inherently describe “repeating evaluating respiration of [a] patient during another first ventilation state *immediately following* evaluating respiration of the patient during [a] second ventilation state.” (Emphasis supplied). Instead, Kück describes evaluating respiration of a patient during a first state (the “before” phase), then a second state (the “during” phase), then a third state (the “after” phase).

Claims 39 and 58 are also allowable because Kück lacks any express or inherent description of evaluating respiration during a first ventilation state that lasts for at least about 30% of a combined duration of the first ventilation state and a second ventilation state. Rather, the description of Kück is limited to evaluating respiration during a “before” phase that lasts for six seconds and during a “during” phase that lasts for about 50 seconds. Thus, the first ventilation state, or “before” phase, lasts for only about one tenth (*i.e.*, about 10%) of the combined duration of the first and second ventilation states, or “before” and “during” phases of the disclosed bi-directional rebreathing process.

Claims 45 and 64 are further allowable because Kück includes no express or inherent description of evaluating respiration of a patient during a second ventilation state in which the patient breathes “gas or a gas mixture comprising at least a concentration of oxygen present in air.” Instead, the description of Kück is limited to a second ventilation state in which a patient breathes gases with an increased concentration of carbon dioxide.

Claim 53 is also allowable since Kück neither expressly nor inherently describes that first and second ventilation states may be effected for substantially a same duration.

Independent claim 70, as amended and presented herein, recites a differential Fick technique that includes a first phase in which a change in the effective ventilation of a patient is induced and a second phase, of substantially the same duration, in which a change in effective ventilation is not present.

Kück does not expressly or inherently describe a differential Fick technique that includes two phases of substantially the same duration. Instead, the description of Kück is limited to a bi-directional rebreathing process that includes a first (“before”) phase, a second (“during”) phase, and a third (“after”) phase. The only description provided in Kück with respect to the lengths of these phases is that the “before” phase lasts for six seconds and the “during” phase lasts for about 50 seconds. *See* col. 9, lines 31-51.

Therefore, it is respectfully submitted that the description provided by Kück does not anticipate each and every element of amended independent claim 70, as would be required to maintain the 35 U.S.C. § 102(e) rejection of that claim.

Claims 77 and 79 are both allowable, among other reasons, for depending directly from claim 70, which is allowable.

Independent claim 84 is also directed to a differential Fick technique. The differential Fick technique of independent claim 84, as amended and presented herein, includes inducing a change in effective ventilation of an individual for a duration of time of about eighteen seconds to about sixty seconds. The change in effective ventilation is then removed for a second duration of time, which lasts for about eighteen seconds to about sixty seconds. The second duration of

time immediately follows the first duration of time. In addition, measurements of at least one respiratory gas and of respiratory flow are obtained during both the first duration and the second duration.

Kück includes no express or inherent description of a Fick technique which includes inducing a change in effective ventilation for a first duration of time, which lasts for about eighteen to about sixty seconds, removing the change in effective ventilation for a second duration of time, which also lasts for about eighteen to about sixty seconds, and obtaining gas and flow measurements during both the first and second durations of time.

It is, therefore, respectfully submitted that the description provided in Kück does not anticipate each and every element of amended independent claim 84 and, thus, that, under 35 U.S.C. 102(e), amended independent claim 84 is directed to subject matter which is allowable of that described in Kück.

Claims 93 and 94 are both allowable, among other reasons, for depending either directly or indirectly from claim 84, which is allowable.

Orr

Claims 34-36, 43-45, 47, 52, 63, 64, 70, 77, 79, 84, 93, 94, 110, and 113-115 stand rejected under 35 U.S.C. § 102(e) for being directed to subject matter which is assertedly anticipated by the description provided in U.S. Patent 6,540,689 to Orr et al. (hereinafter "Orr").

Orr describes various techniques for improving the accuracy with which pulmonary capillary blood flow, cardiac output, and other parameters may be noninvasively determined. These techniques include monitoring respiration during various phases of a bi-directional rebreathing process (*i.e.*, before, during, and after rebreathing). Orr lacks any express or inherent description of the durations of each of these phases, however.

Thus, with respect to the subject matter recited in amended independent claims 34, 52, and 110, Orr does not expressly or inherently describe a method which includes evaluating respiration during first and second ventilation states (claims 34 and 52) or phases (claim 110) that each last for about eighteen seconds to about sixty seconds.

Additionally, with respect to amended independent claim 84, Orr includes no express or inherent description of a Fick technique which includes inducing a change in effective ventilation for a first duration of time, which lasts for about eighteen to about sixty seconds, removing the change in effective ventilation for a second duration of time, which also lasts for about eighteen to about sixty seconds, and obtaining gas and flow measurements during both the first and second durations of time.

Further, with respect to amended independent claim 70, Orr does not expressly or inherently describe a differential Fick technique that includes two phases of substantially the same duration.

As Orr does not anticipate each and every element of any of amended independent claims 34, 52, 70, 84, or 110, it is respectfully submitted that, under 35 U.S.C. § 102(e), each of these claims is drawn to subject matter which is allowable over that described in Orr.

Each of claims 35, 36, 43-45, and 47 is allowable, among other reasons, for depending directly or indirectly from claim 34, which is allowable.

Claims 63 and 64 are both allowable, among other reasons, for depending directly from claim 52, which is allowable.

Claims 77 and 79 are both allowable, among other reasons, for depending directly from claim 70, which is allowable.

Claims 93 and 94 are both allowable, among other reasons, for depending either directly or indirectly from claim 84, which is allowable.

Claims 113-115 are each allowable, among other reasons, for depending directly or indirectly from claim 110, which is allowable.

Claim 36 is additionally allowable since Orr does not expressly or inherently describe “repeating evaluating respiration of [a] patient during another first ventilation state *immediately following* evaluating respiration of the patient during [a] second ventilation state.” (Emphasis supplied). Instead, Orr describes evaluating respiration of a patient during a first state (the “before” phase), then a second state (the “during” phase), then a third state (the “after” phase).

Claims 45 and 64 are further allowable because Orr includes no express or inherent description of evaluating respiration of a patient during a second ventilation state in which the

patient breathes “gas or a gas mixture comprising at least a concentration of oxygen present in air.” Instead, the description of Orr is limited to a second ventilation state in which a patient breathes gases with an increased concentration of carbon dioxide.

In view of the foregoing, it is respectfully requested that the 35 U.S.C. § 102(e) rejections of claims 34-36, 38-41, 43-45, 47, 52, 53, 58-61, 63, 64, 70, 77, 79, 84, 93, 94, 110, and 113-115 be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

Claims 37, 38, 41, 54-57, 71-74, 76, 88-92, and 112 have been rejected under 35 U.S.C. § 103(a).

Mault

Claims 37 and 41 stand rejected under 35 U.S.C. § 103(a) for reciting subject matter which is purportedly unpatentable over the teachings of Mault.

Claims 37 and 41 are both allowable, among other reasons, for depending directly from claim 34, which is allowable.

Claim 41 is further allowable because, before the filing date of the above-referenced application, one of ordinary skill in the art would not have been motivated to conduct a rebreathing or similar cycle in less than two minutes. As evidenced by much of the art that has been made of record in the above-referenced application, large sample times have conventionally been used to provide a large number of data samples and to accurately establish baseline values and values that accompany a change in the effective ventilation of a patient.

Based on the state of the art before the above-referenced application was filed, it appears that the only way in which one of ordinary skill in the art could have been motivated to modify the teachings of Mault in the manner that has been asserted would have been through improper reliance upon the hindsight provided by the above-referenced application.

Kück

Claims 37, 38, 54-57, 71-74, 76, 88-92, and 112 stand rejected under 35 U.S.C. § 103(a) for being directed to subject matter which is allegedly unpatentable over the subject matter taught in Kück.

Claims 37, 38, and 41 are each allowable, among other reasons, for depending directly from claim 34, which is allowable.

Claim 41 is further allowable because, for the reasons provided above in reference to the 35 U.S.C. § 103(a) rejection of claim 41 as being obvious over the teachings of Mault, one of ordinary skill in the art would not have been motivated to shorten the duration of a rebreathing cycle to less than two minutes.

Claims 54-57 are each allowable, among other reasons, for depending directly or indirectly from claim 52, which is allowable.

Claim 54 is further allowable since Kück neither teaches nor suggests that any of the “before,” “during,” or “after” phases of the bi-directional rebreathing technique disclosed therein may have substantially the same duration as another of these phases.

Each of claims 71-74 is allowable, among other reasons, for depending directly from claim 70, which is allowable.

Claim 71 is further allowable since Kück lacks any teaching or suggestion of first and second phases that are substantially the same. As noted previously herein, the duration of the six second “before” phase disclosed in Kück is only about ten percent of the combined durations of the “before” phase with a “during” phase that lasts for about 50 seconds. Based on this disparity between the lengths of these two phases, it is respectfully submitted that one of ordinary skill in the art would not have been motivated to modify the teachings of Kück in the manner that has been asserted to come up with a method that includes “before” and “during” phases that are substantially the same. Moreover, the Office has not met its burden of setting forth support for the assertion that one of ordinary skill in the art would have been motivated to modify the teachings of Kück in the asserted manner.

Due to the disparity between the durations of the “before” and “during” phases, it also appears that any such motivation could only have been improperly gleaned from the hindsight provided by the above-referenced application.

Claim 72 is further allowable since neither the “before” phase of the bi-directional rebreathing method taught in Kück nor the “during” phase of that method lasts for “about 30 seconds.” Again, the only specifics that Kück provides with respect to the durations of these phases are that the “before” phase lasts for six seconds and the “during” phase lasts for about 50 seconds.

Claim 74 is allowable since the “before” phase of the bi-directional rebreathing method taught in Kück, in which a change in effective ventilation is not induced, lasts for roughly one tenth of the combined duration of the “before” and “during” phases, not for at least about 30% of the combined duration.

Each of claims 88-92 is allowable, among other reasons, for depending directly or indirectly from claim 84, which is allowable.

Claim 88 is further allowable since Kück lacks any teaching or suggestion of first and second phases that are substantially the same. As noted previously herein, the duration of the six second “before” phase disclosed in Kück is only about ten percent of the combined durations of the “before” phase with a “during” phase that lasts for about 50 seconds. Based on this disparity between the lengths of these two phases, it is respectfully submitted that one of ordinary skill in the art would not have been motivated to modify the teachings of Kück in the manner that has been asserted to come up with a method that includes “before” and “during” phases that are substantially the same. Moreover, the Office has not met its burden of setting forth support for the assertion that one of ordinary skill in the art would have been motivated to modify the teachings of Kück in the asserted manner.

Due to the disparity between the durations of the “before” and “during” phases, it also appears that any such motivation could only have been improperly gleaned from the hindsight provided by the above-referenced application.

Claim 90 is additionally allowable because the “before” phase of the bi-directional rebreathing method taught in Kück, in which a change in effective ventilation is not induced, lasts for roughly one tenth of the combined duration of the “before” and “during” phases, not for at least about 30% of the combined duration.

Claim 91 is further allowable since Kück does not teach or suggest that both the “before” and “during” phases may last for about thirty seconds.

Claim 112 is allowable, among other reasons, for depending directly from claim 110, which is allowable. In addition, claim 112 is allowable since Kück lacks any teaching or suggestion of first and second phases that are substantially the same. As noted previously herein, the duration of the six second “before” phase disclosed in Kück is only about ten percent of the combined durations of the “before” phase with a “during” phase that lasts for about 50 seconds. Based on this disparity between the lengths of these two phases, it is respectfully submitted that one of ordinary skill in the art would not have been motivated to modify the teachings of Kück in the manner that has been asserted to come up with a method that includes “before” and “during” phases that are substantially the same. Moreover, the Office has not met its burden of setting forth support for the assertion that one of ordinary skill in the art would have been motivated to modify the teachings of Kück in the asserted manner.

Again, due to the disparity between the durations of the “before” and “during” phases, it also appears that any such motivation could only have been improperly gleaned from the hindsight provided by the above-referenced application.

For these reasons, withdrawal of the 35 U.S.C. § 103(a) rejections of claims 37, 38, 41, 54-57, 71-74, 76, 88-92, and 112 is respectfully requested.

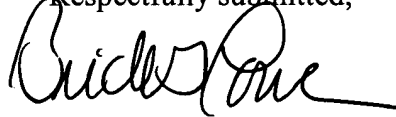
CONCLUSION

It is respectfully submitted that each of claims 34-120 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of

Serial No. 09/813,225

the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Brick G. Power", with a long horizontal flourish extending to the right.

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